SECTION 5 510(k) SUMMARY

510(k) Summary for K130909: Gateway™ Advantage Y-Adapter

MAY 16 2013

A. Sponsor

Boston Scientific Corporation
Urology and Women's Health Division
100 Boston Scientific Way
Marlborough, MA 01756

B. Contact

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508-683-4214
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or

Lisa Sullivan
Manager, Regulatory Affairs
508-683-4745
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C. Device Name

Trade name: Gateway™ Advantage Y-Adapter
Common/usual name: Endoscope and accessories
Classification Name: OCX – Endoscopic Irrigation/Suction System

D. Predicate Device

Trade name: Sureseal II (Applied Medical)
Common/usual name: Endoscope and accessories
Classification Name: KOG – Endoscope and accessories

Premarket Notification: Applied Medical Sureseal II (formerly Applied Urology, Inc. Sureseal Endoscopic Valve), K920030, March 18, 1992.

E. Device Description

The Gateway Advantage Y-Adapter has four main components; 1) a rotatable male luer fitting; 2) a Y-Adapter body; 3) a thumb screw Tuohy-Borst valve; and 4) a blue luer seal with female proximal end. The body has two lumens: a straight lumen and an adjoining curved lumen. The straight lumen tapers to an inner diameter of 3 mm (9 F) minimum, and the adjoining curved lumen tapers to an inner diameter of 2.413 mm (7 F) minimum. The adjoining curved lumen is terminated at the proximal end with a blue luer seal and the straight lumen of the Y-Adapter body has a Tuohy-Borst valve. Both valve and seal are intended to prevent irrigant backflow and secure urological devices. The blue luer seal has a

female proximal end intended for use with irrigant tubing with a male luer connection. The distal end of the straight lumen has a rotating male luer which attaches to the scope.

F. Intended Use

The Gateway Advantage Y-Adapter is intended to prevent irrigant backflow while securing urological devices during procedures. Irrigation may also be connected to the side port of the device.

G. Technological Characteristics

The Gateway Advantage Y-Adapter has the same technological characteristics and fundamental adapter design as the reference devices. The proposed Gateway Advantage Y-Adapter is supplied in a sealed pouch and intended for single use only. It is available for use with other urology products, such as retrieval baskets, guidewires, catheters, laser fibers and other urological instruments. The device is packaged 1 per pouch, with 10 pouches packaged per box.

H. Substantial Equivalence

A direct comparison of key characteristics has been performed and demonstrates that the proposed Gateway Advantage Y-Adapter is substantially equivalent to the predicate device in terms of intended use. The proposed device is substantially equivalent to the reference devices in terms of technological characteristics, materials and performance characteristics. The Gateway Advantage Y-Adapter is as safe, as effective, and performs as well as the predicate device.

I. Performance Testing (Bench Evaluation)

Boston Scientific has conducted performance testing with samples aged at T=0. Accelerated Aging in support of a 3-year shelf life was also performed. The following testing was completed to evaluate the device:

- Leak Resistance with Urologic Device
- Leak Resistance After Removal of Urologic Device
- Tuohy-Borst – Acceptance of Multiple Exchanges
- Luer Seal – Acceptance of Multiple Exchanges
- Securing Device – Removal Force

The results of the performance testing demonstrate equivalence of the Gateway Advantage Y-Adapter to the predicate Sureseal II Endoscopic Valve. The Gateway Advantage Y-Adapter is considered safe and effective for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

May 16, 2013

Boston Scientific Corporation
Urology/Women's Health
% Ms. Christine Shoemaker
Specialist II, Regulatory Affairs
100 Boston Scientific Way
MARLBOROUGH MA 01752

Re: K130909
Trade/Device Name: Gateway™ Advantage Y- Adapter
Regulation Number: 21 CFR§ 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: OCX
Dated: March 29, 2013
Received: April 1, 2013

Dear Ms. Shoemaker:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Benjamin R. Fisher -S

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

SECTION 4 **INDICATIONS FOR USE**

Indications for Use Statement

510(k) Number	K130909
Device Name	Gateway™ Advantage Y-Adapter
Indications For Use	The Gateway Advantage Y-Adapter is intended to prevent irrigant backflow while securing urological devices during procedures. Irrigation may also be connected to the side port of the device. The Y-Adapter is supplied in a sealed pouch and is intended for single use only.

Prescription Use__X___ (21 CFR 801 Subpart D) AND/OR Over-The-Counter Use_____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Benjamin R. Fisher -S
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(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K130909